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EXAMINER

SAJJADI, FEREDYDOUN GHOTB

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ADVISORY ACTION

Continuation of 11. does NOT place the application in condition for allowance because: Applicants have cancelled claims 1, 3, 10, 11, 14, 17, 18, 24 and 25, thus rendering their rejection under 35 USC §112, first paragraph, moot. Claims 4 and 15 have been amended. The claim cancellations and amendments further obviate the objection to claims 3, 15, 17 and 25. The Examiner maintains the rejection of claims 4, 6-8, 15, 26 and 27 under 35 USC §112, first paragraph, scope of enablement; for reasons of record. The proposed claim amendments and arguments, while addressing certain issues related to the rejection, that include the lack of expression vectors and route of delivery, fail to overcome the remaining grounds for rejection.

Applicants argue that claim 4, which is directed to a method of inducing apoptosis of prostate cancer cells or breast cancer cells in a tumor in a subject, has been amended to recite that the nucleic acid is in a viral vector and is delivered to these cells by intratumoral injection. Since claim 4 is not directed at a method of preventing metastasis of these cancer cells, and since applicants have shown intratumoral injection of a KChAP nucleic acid that has been incorporated into a viral expression vector works, i.e., induces apoptosis of such cells, the method recited in claim 4, as amended, meets the enablement requirement of 35 USC §112, first paragraph. Applicants' arguments have been fully considered, but are not found persuasive.

With regard to the amendment of base claim 4 to recite that the nucleic acid is in a viral vector, it is noted that the claim fails to recite that the KChAP nucleic acid is operably linked to a promoter active in the cancer cells. While such language is present in dependent claim 6, it is absent in the base claim.

Additional issues relate to the use of cell lines (as opposed to primary tumor cells) and ectopic and heterotopic transplantation of said cell lines (versus orthotopic transplantation or primary tumor cells) in immunodeficient nude mice, as well as the paradox that enhancement of K^+ channel activity can facilitate not only tumor cell apoptosis but also tumor cell proliferation, especially in a tumor mass comprising a mixed cell population. As previously indicated, the heterotopic subcutaneous xenotransplantation of cell lines in an immunodeficient mouse fails to reflect human carcinoma.

The rejection of the claims is thus maintained in view of the foregoing issues.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fereydoun G. Sajjadi, Ph.D.
Examiner, Art Unit 1633

/Anne Marie S. Wehbe/
Primary Examiner, Art Unit 1633